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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,759	10/14/2003	Li Wang	P0011118.00	3360

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MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MINNEAPOLIS, MN 55432-9924

EXAMINER

ALTER, ALYSSA MARGO

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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01/29/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/684,759	Applicant(s) WANG ET AL.	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-106 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 72-106 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 72, 74, 78-79, 87, 89, 93-94 and 103-106 are rejected under 35 U.S.C. 102(b) as being anticipated by Combs et al. (US 5,957,861 A). Combs et al. discloses a system to produce impedance measurements in a subcutaneous portion of the body with at least two electrodes. "Also depending on the location of the electrodes used for measurement, it is wise to consider synchronization to the heart beat cycle and the respiratory cycles or the variation in measurement resulting from measuring at inconsistent times within these cycles may cause insurmountable difficulties in extracting useful signal from the impedance changes created by these cycles. (col. 6, lines 51-57). Therefore, since the impedance measurements are synchronized with the cardiac cycle, they are responsive to a cardiac event.

"The determination of pulmonary edema or local edema will be based upon comparison of long term average impedance value compared to the short term average value" (col. 9, lines 64-67). "A determination of how severe the disease is by how

quickly the edema progresses (i.e. if the change was seen over the course of two weeks, versus one day) becomes a measure that has value to the patient and physician and can be a stored value kept in a memory circuit by a device made in keeping with this invention”(col. 9, lines 53-59). Furthermore, “Long term average preferably represents the number of days (in the most preferred embodiment three to thirty) while the short term average represents the number of hours (preferably one to forty-eight)”(col. 10, lines 14-18).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 76-77, 91-92 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Combs et al. (US 5,957,861 A). Combs et al. discloses that the impedance measurements are synchronized with the cardiac cycle and thus they are triggered by a cardiac event. Therefore, the system of Combs et al. would inherently perform an impedance measurement within 10-30 ms of a sensed cardiac event.

In the alternative, although the examiner considers Combs et al. to disclose delivering an impedance measurement pulse within 10-30 ms of a sensed cardiac event, it would have been obvious to one having ordinary skill in the art at the time the

invention was made to have modified the interval after the pacing pulse to be within 10 to 30 milliseconds in order to provide the predictable results of modifying the treatment to meet specific patient needs. Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05).

2. Claims 73, 75, 80-86, 88, 90, 95-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Combs et al. (US 6,512,949 B1). Combs et al. discloses the claimed invention except for the system possessing a sense amplifier with a blanking period and the system delivering an impedance measuring pulse during the blanking period. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have included a sense amplifier with a blanking period for delivering an impedance measurement pulse during the blanking period in order to provide the predictable results of preventing inadvertent stimulation of the heart of other tissue when trying to assess an impedance value.

As to claims 80-84 and 95-100, Combs et al. discloses the claimed invention except for assessing the integrity of the leads. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system to include a means for determining the integrity of the leads in order to provide the predictable results of ensuring the components of the system, i.e. the leads, are in proper working order. Furthermore, checking the integrity of the leads would ensuring the sensed values are accurate.

As to claims 85-86 and 101-102, Combs et al. discloses the claimed invention except for the performance of a cross-check or employing the cross check of the measured impedance value to determine if the data is valid or flawed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the collection of impedance data to include a means for cross-checking impedance data since such a modification would provide the predictable results of ensuring the accuracy of the data collected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762